K033094

DEC 1 9 2003

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085
Phone: (408) 732-3856
Fax: (408) 732-3849

Contact: Cheng-I Lin, Ph.D.
President, R&D Director

Device Name and Classification

Classification Name:	Enzyme Immunoassay, Amphetamine, Class II, DKZ (91 Toxicology), 21CFR 862.3100
Common Name:	Homogeneous enzyme immunoassay for the determination of Ecstasy (MDMA) levels in urine.
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Ecstasy Enzyme Immunoassay is substantially equivalent to the DRI Ecstasy Assay (By Microgenics Corp.), cleared under premarket notification K012110.

LZI's Ecstasy Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

LZI's Ecstasy Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibody that can detect Ecstasy (MDMA) in human urine with minimal cross-reactivity to various, common prescription drugs and abused drugs.

The assay is based on competition between ecstasy labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme and free drug from the urine sample for a fixed amount of specific antibody. In the absence of free drug from the urine sample the specific antibody binds to the drug labeled with G6PDH enzyme causing a decrease in enzyme activity. The G6PDH enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to covert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use

The Ecstasy Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 500 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of Ecstasy (MDMA) in human urine.

Comparison to Predicate Device

LZI's Ecstasy Enzyme Immunoassay is substantially equivalent to other products in commercially distribution intended for similar use. Most notably it is substantially equivalent to the currently, commercially marketed DRI Ecstasy Assay (K012110) by Microgenics Corporation.

The following table compares LZI's Ecstasy Enzyme Immunoassay with the predicate device, DRI Ecstasy Enzyme Immunoassay by Microgenics Corp.

Similarities:

- Both assays are for qualitative and semi-quantitative determination of Ecstasy in human urine.
- Both assays use 500 ng/mL cutoff, and 5 points calibration for semi-quantitative determination.
- Both assays use the same method principle, and device components.

Differences:

- Microgenics assay uses 5 points calibration (0, 250, 500, 750, 1000 ng/ml) for semi-quantitative determination. LZI assay uses 5 calibrator set (0, 100, 500, 750, and 1000 ng/ml) for semi-quantitative determination.

(Comparison to Predicate Device, continued)

Performance Characteristics

Feature	DRI's Ecstasy EIA				LZI's Ecstasy EIA			
Within Run Precision:								
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	375 ng/mL	254	2.3	0.9	Negative	254.4	2.28	0.90
	500 ng/mL	332	3.4	1.0	375 ng/mL	327.9	2.50	0.76
	625 ng/mL	395	3.8	1.0	500 ng/mL	384.2	3.13	0.81
					625 ng/mL	420.8	3.54	0.84
		Mean Conc.	SD	% CV	1000 ng/mL	453.5	3.27	0.72
Semi-quantitative:	375 ng/mL	359	5.7	1.6		Mean Conc.	SD	% CV
	500 ng/mL	500	6.9	1.4	375 ng/mL	381.4	5.24	1.37
	625 ng/mL	630	9.5	1.5	500 ng/mL	517.4	8.05	1.56
					625 ng/mL	649.0	11.38	1.75
Run-To-Run Precision:								
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	375 ng/mL	254	7.0	2.8	Negative	252.4	2.37	0.94
	500 ng/mL	332	8.9	2.7	375 ng/mL	326.9	2.55	0.78
	625 ng/mL	395	7.2	1.8	500 ng/mL	383.2	1.20	0.31
					625 ng/mL	420.3	3.31	0.79
					1000 ng/mL	453.6	3.39	0.75
Semi-quantitative:		Mean Conc.	SD	% CV		Mean Conc.	SD	% CV
	375 ng/mL	359	9.1	2.5	375 ng/mL	367.6	8.73	2.37
	500 ng/mL	500	10.7	2.1	500 ng/mL	502.6	9.46	1.88
	625 ng/mL	630	2.1	2.2	625 ng/mL	637.1	8.21	1.29
Sensitivity:	22 ng/mL				50 ng/mL			
Accuracy:					Vs. GC/MS (n=127)			
Positive Samples:	100 % agreement (GC/MS confirmed)				97% agreement			
Negative Samples:	100 % agreement				100 % agreement			
Analytical Recovery:								
Qualitative:	No data available				100 % accuracy on positive vs. negative tests			
Semi-quantitative:	No data available				Quantitates within ±10% of the nominal concentration between 50 ng/mL and 920 ng/mL.			
Specificity:	See attached DRI's Ecstasy EIA package insert				Comparable to the predicate device.			

Conclusion

LZI's Ecstasy Enzyme Immunoassay was evaluated for several performance characteristics including precision, sensitivity, accuracy, analytical recovery, and specificity. All the studies showed acceptable results when compared to the predicate device.

We trust the information provided in this Premarket Notification [510(k)] submission will support a determination of substantial equivalence of the LZI's Ecstasy Enzyme Immunoassay to other Ecstasy test systems currently marketed in the United States.

510(k) Summary of Safety and Effectiveness

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Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085
Phone: (408) 732-3856
Fax: (408) 732-3849

Contact: Cheng-I Lin, Ph.D.
President

Device Name and Classification

(a) Classification Name: Calibrators, Drug Specific;
Class II, DLJ (91 Toxicology), 21 CFR 862.3200
Common/Usual Name: Ecstasy Calibrators
Proprietary Name: None

(b) Classification Name: Single (Specified) Analyte Controls (Assayed and Unassayed);
Class I, LAS (91 Toxicology), 21 CFR 862.3280
Common/Usual Name: Ecstasy Controls
Proprietary Name: None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Ecstasy Drug of Abuse Calibrators and Controls are substantially equivalent to the DRI Ecstasy Urine Calibrators and controls, by Microgenics Corporation, cleared under premarket notifications (K012109).

Device Description

All of the Single Analyte Urine DAU Calibrators and Controls are human urine-based liquid, and ready to use. These Calibrators and Controls do not have any especially unique technical characteristics. Each contains a known concentration of a specific drug analyte.

The Negative DAU calibrator is a processed, drug-free human urine matrix, which has also been used with all assays. The calibrators and controls are prepared by spiking known concentrations of drug analyte into the Negative DAU Calibrator matrix. The concentrations of drug analyte in the calibrators and controls are summarized as follows:

	Ecstasy EIA
Reference Material	MDMA
Negative Calibrator	0 ng/mL
Low Calibrator	100 ng/mL
Cutoff Calibrator	500 ng/mL
Intermediate Calibrator	750 ng/mL
High Calibrator	1000 ng/mL
Control Level I	375 ng/mL
Control Level II	625 ng/mL

Intended Use

The Ecstasy DAU Calibrators are intended for in vitro diagnostic use for the calibration of the Ecstasy enzyme immunoassay to detect ecstasy in human urine.
The Ecstasy DAU Controls are intended for in vitro diagnostic use for the validation of the Ecstasy enzyme immunoassay to detect ecstasy in human urine.

Comparison to Predicate Device

LZI's Ecstasy DAU Calibrators and Controls are similar in intended use, matrix, and performance to the DRI's ecstasy calibrators and controls included in the DRI Ecstasy Calibrators and Controls.

Similarities:

- Both are for the calibration and validation of Ecstasy Enzyme Immunoassay to detect drug of abuse in human urine.
- A total of 5 levels of calibrators including the negative calibrator for each analyte.
- The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.
- Both are urine-based liquids.
- Storage condition is the same, at 2°C to 8°C.
- Performance characteristics on precision, accuracy and stability are similar.

Differences:

- For semi-quantitative assay, DRI uses 0, 250, 500, 750, and 1000 ng/mL as calibrators. LZI uses 0, 100, 500, 750, and 1000 ng/mL as calibrators.

Conclusion

The information provided in the premarket notification demonstrates that the LZI's Ecstasy Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to previously approved predicate devices, notably the DRI Ecstasy Urine Calibrators and Controls, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2003

Cheng-I Lin, Ph.D.
President, R & D Director
Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085

Re: k033094
Trade/Device Name: Ecstasy Enzyme Immunoassay
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: DJC; DLJ; LAS
Dated: September 25, 2003
Received: September 29, 2003

Dear Dr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Premarket Notification Supplement

Indications for Use Statement

510(k) Number (if known): K033094

Device Name: Ecstasy Drug of Abuse Calibrators and Controls

Indications for Use:

The Ecstasy Drug of Abuse Calibrators are intended for in vitro diagnostic use for the calibration of the Ecstasy enzyme immunoassay to detect ecstasy drugs in human urine.

The Ecstasy Drug of Abuse Controls are intended for in vitro diagnostic use for the validation of the Ecstasy enzyme immunoassay to detect ecstasy drugs in human urine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033094

Premarket Notification

Indications for Use Statement

510(k) Number (if known): K033094

Device Name: Ecstasy Enzyme Immunoassay

Indications for Use:

The Ecstasy Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 500 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of Ecstasy (MDMA) in human urine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The Ecstasy Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033094

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)